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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,415	06/26/2006	Yasuomi Urano	062522	9423

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

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06/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,415	URANO ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are presented for examination.

Upon further consideration of the claimed subject matter, the restriction requirement of November 5, 2007 has been VACATED in lieu of the following requirement, which supersedes the previous requirement of November 5, 2007.

Instant claims 10-14 provide for the use of a cholesterol synthesis inhibitor or a protein geranylgeranylation regulator for producing an inhibitor for the formation of a γ-secretase complex, but fail to set forth whether such claims are intended to circumscribe a (1) process of use (i.e., for forming a γ-secretase complex), (2) process of making (i.e., for producing an inhibitor for the formation of a γ-secretase complex) or (3) product (i.e., cholesterol synthesis inhibitor or a protein geranylgeranylation regulator). For the purposes of restriction, present claims 10-14 will be interpreted alternatively as (1) a process of use for forming a γ-secretase complex, (2) a process of producing an inhibitor for the formation of a γ-secretase complex or (3) a product of a cholesterol synthesis inhibitor or a protein geranylgeranylation regulator. Applicant is reminded that "use" claims are non-statutory under U.S. patent practice and may wish to consider amending the claims to obviate any issues that may be raised under 35 U.S.C. 101 and/or 35 U.S.C. 112, second paragraph, for being directed to a non-statutory category of invention.

Requirement for Election/Restriction

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4 and 10-14, drawn to an inhibitor for the formation of a γ-secretase complex comprising a cholesterol synthesis inhibitor or a protein geranylgeranylation regulator.

Group II, claim(s) 5-9, drawn to a method of inhibiting the formation of an active complex of γ-secretase using a cholesterol synthesis inhibitor or a protein geranylgeranylation regulator.

Group III, claim(s) 10-14, drawn to a method for producing an inhibitor for the formation of a γ-secretase complex using a cholesterol synthesis inhibitor or a protein geranylgeranylation regulator.

Group IV, claim(s) 10-14, drawn to a method for forming a γ-secretase complex using a cholesterol synthesis inhibitor or a protein geranylgeranylation regulator.

Group V, claim(s), 15-18, drawn to a method of screening a substance having an effect of inhibiting the formation of an active complex of γ-secretase comprising assaying an activity of inhibiting cholesterol synthesis.

Group VI, claim(s) 19-21, drawn to a method of screening a cholesterol synthesis inhibitor, a protein geranylgeranylation regulator or an HMG-CoA reductase inhibitor, comprising screening an effect of inhibiting the formation of an active complex of γ-secretase.

Group VII, claim(s) 22-23, drawn to a method of screening an effect of a test substance on γ-secretase comprising measuring the distribution of constituents required by γ-secretase in the cell for the formation of an active complex thereof by adding the test substance to cultured cells.

The inventions listed as Group I-IV and VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: the use of a cholesterol synthesis inhibitor, such as, e.g., an HMG-CoA reductase inhibitor, was known in the prior art [see, e.g., Wolozin (*Biochemical Society Transactions,* 2002, Volume 30, p.525529, which discloses an HMG-CoA reductase inhibitor] and, thus, cannot be considered the unifying feature of the inventions of Groups I-IV and VI because it fails to demonstrate a contribution over what was already known in the prior art at the time of the invention.

Furthermore, the inventions listed as Groups V and VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: the invention listed as Group V requires the step of assaying the activity of a substance in inhibiting cholesterol synthesis, which is not required for the practice of the inventions of Group VII and the invention listed as Group VII requires the step of measuring the distribution of constituents required by γ-secretase in the cell for the formation of an active complex

thereof by adding the test substance to cultured cells, which is not required for the practice of the invention of Group V. For these reasons, the inventions listed as Groups V and VII fail to share a common special technical feature and, thus, also fail to set forth a single general inventive concept.

Moreover, since the special technical feature of the inventions listed as Groups I-IV and VI is not the same feature(s) shared by the inventions listed as Groups V-VII, the inventions listed as Groups I-VII fail to share a common special technical feature among each of the claimed inventions and, as a result, do not relate to a single general inventive concept for this reason.

Election of Invention I, II, III, IV or VI requires Applicant to make the following species elections:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is required to elect a **single disclosed specie** of cholesterol synthesis inhibitor or protein geranylgeranylation regulator from those specifically claimed (see, e.g., instant claims 2, 7, 12 or 20) or from those specifically disclosed at p.11, l.16-22 of the instant specification.

Should Applicant elect an HMG-CoA reductase inhibitor as the single disclosed specie of cholesterol synthesis inhibitor or protein geranylgeranylation regulator for examination on the merits, Applicant is further required to elect a **single disclosed specie** of HMG-CoA reductase inhibitor from those specifically disclosed at p.12, l.4-p.13, l.20.

For example, if Applicant elects HMG-CoA reductase inhibitors as the single disclosed specie of cholesterol synthesis inhibitor or protein geranylgeranylation regulator for examination on the merits, then an appropriate election of a single disclosed specie of HMG-CoA reductase inhibitor would be pitavastatin as disclosed at p.13 of the instant specification.

Applicant is cautioned that the election of a particular specie of compound, wherein the elected specie(s) is/are not adequately supported by the accompanying specification, may raise an issue of new matter under the written description requirement of 35 U.S.C. 112, first paragraph.

The following claims are generic: claims 1-23.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical feature for the following reasons: the use of a cholesterol synthesis inhibitor, such as, e.g., an HMG-CoA reductase inhibitor, was known in the prior art [see, e.g., Wolozin (*Biochemical Society Transactions,* 2002, Volume 30, p.525529, which discloses an HMG-CoA reductase inhibitor] and, thus, cannot be considered the unifying feature of the inventions of Groups I-IV because it fails to demonstrate a contribution over what was already known in the prior art at the time of the invention.

Furthermore, regarding the species of cholesterol synthesis inhibitors or protein geranylgeranylation regulators, such genera of agents encompass such a breadth of compounds that are structurally and/or chemically distinct and/or dissimilar from any one single other compound from any one single other generic formula encompassed by the claims such that a comprehensive search of the patent and non-patent literature for any one such compound would not necessarily result in a comprehensive search of any one or more of the other compounds within the claimed genus. Furthermore, in consideration of the number and breadth of compounds contained within each genera, the disparate nature and breadth of compounds encompassed by each of the claimed genera precludes a quality examination on the merits, not only because a burdensome search would be required for the entire scope of the claim(s), but also because the consideration of the findings of such a search for compliance

with the statutes and requirements set forth under 35 U.S.C. 101, 102, 103 and 112, would be unduly burdensome.

Applicant is advised that a reply to this requirement is REQUIRED to include an (1) identification of the invention for examination on the merits, (2) identification of the single disclosed species elected consonant with the requirements set forth *supra* and (3) a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please reference MPEP §809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though this requirement be traversed (37 C.F.R. 1.143) and (ii) an identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the

inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the Examiner withdraws the restriction requirement before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

May 29, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614